New GEM-3 Phase 3 Results for B-VEC Presented at 2022 American Academy of Dermatology Annual Meeting

March 26, 2022

PITTSBURGH, March 26, 2022 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc., ("Krystal Biotech") (NASDAQ: KRYS), the leader in redosable gene therapies for rare diseases, presented more detailed results from the GEM-3 Phase 3 study of beremagene geperpavec (B-VEC), an investigational, topical gene therapy, for the treatment of dystrophic epidermolysis bullosa (DEB), at the 2022 American Academy of Dermatology Annual Meeting in Boston, Mass.

The data was presented by Peter Marinkovich, M.D., Director of the Blistering Disease Clinic at Stanford Health Care and Associate Professor of Dermatology at the Stanford University School of Medicine and primary investigator of the GEM-3 study, during the late-breaking research session. The full presentation is available in the Investors section of Krystal Biotech's website.

"We are very pleased to share this data at such a highly regarded dermatology conference," said Suma Krishnan, President, Research & Development, Krystal Biotech. "Following the initial report of the topline results, the latest data lend further strong support for our belief that B-VEC could correct this devastating disease at the molecular level and fulfill our founding mission to bring a convenient, non-invasive treatment to EB patients and their families."

The GEM-3 trial was a multicenter, randomized, double-blind, placebo-controlled intra-patient study evaluating the efficacy and safety of B-VEC in 31 patients with DEB. As previously announced, B-VEC met the primary and secondary efficacy endpoints in complete wound healing relative to placebo. The proportion of primary wounds with complete wound healing was significantly greater with B-VEC than placebo at both 3- and 6-month timepoints ($p < 0.005$). The long-term use of B-VEC is being further investigated in an ongoing open-label extension study (NCT04917874), regardless of prior enrollment in GEM-3.

Investor Conference Call, Webcast and Presentation Information
Krystal Biotech will host an investor conference call and webcast on Monday, March 28, at 8:00 a.m. EDT, to discuss the more detailed results from the GEM-3 Phase 3 study. To participate in the conference call, please dial 1-877-269-7751 (domestic) or 1-201-389-0908 (international) and refer to conference ID 13727856. The webcast, which will include presentation slides, will be available live and for replay in the Investors section of Krystal Biotech's website and can be accessed directly here.

About Dystrophic Epidermolysis Bullosa (DEB)
DEB is a rare and severe disease that affects the skin and mucosal tissues. It is caused by one or more mutations in a gene called *COL7A1*, which is responsible for the production of the protein type VII collagen (COL7) that forms anchoring fibrils that bind the dermis (inner layer of the skin) to the epidermis (outer layer of the skin). The lack of functional anchoring fibrils in DEB patients leads to extremely fragile skin that blisters and tears from minor friction or trauma. DEB patients suffer from open wounds, which leads to skin infections, fibrosis which can cause fusion of fingers and toes, and ultimately an increased risk of developing an aggressive form of squamous cell carcinoma which, in severe cases, can be fatal.

About B-VEC
B-VEC is an investigational non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. B-VEC was designed to treat DEB at the molecular level by providing the patient's skin cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism.

The FDA and the EMA have each granted B-VEC orphan drug designation for the treatment of DEB, and the FDA has granted B-VEC fast track designation and rare pediatric designation for the treatment of DEB. In addition, in 2019, the FDA granted Regenerative Medicine Advanced Therapy ("RMAT") to B-VEC for the treatment of DEB and the EMA granted PRIority MEdicines ("PRIME"), eligibility for B-VEC to treat DEB.

About Krystal Biotech
Krystal Biotech, Inc. (NASDAQ:KRYS) is a pivotal-stage gene therapy company leveraging its proprietary, redosable gene therapy platform and in-house manufacturing capabilities to potentially bring life-changing treatment options to patients with serious diseases, including rare diseases in skin, lung, and other areas. For more information, please visit http://www.krystalbio.com and follow @KrystalBiotech on LinkedIn and Twitter.

Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including but not limited to statements about the clinical utility of B-VEC and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors as are set forth under the caption "Risk Factors" in Krystal Biotech's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Krystal Biotech's views as of the date of this press release. Krystal Biotech anticipates that subsequent events and developments will cause its views to change. However, while Krystal Biotech may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Krystal Biotech's views as of any date subsequent to the date of this press release.

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